

Appln. No. 09/893,005  
Amd. dated January 28, 2005  
Reply to Office Action of November 2, 2004

REMARKS

The Office Action and the cited and applied references have been carefully reviewed. No claim is allowed. Claims 11-16, 18-21, and 32 presently appear in this application and define patentable subject matter warranting their allowance. Reconsideration and allowance are hereby respectfully solicited.

Claims 20 and 21 are now amended to be directed to the elected grown-up transgenic plant. Accordingly, claims 20 and 21 should be examined on the merits along with the other elected claims.

Claims 11-16, 18-19 and 32 have been rejected under 35 U.S.C. §112, second paragraph, because the recitation of "grown-up" is considered to be indefinite by the examiner. This rejection is respectfully traversed.

With due respect to the examiner, it is believed that the examiner has mistakenly associated the definition of the verb "grow" with the definition of the adjective "grown-up" on page 619 of the cited and submitted relevant pages of Webster's New World Dictionary of the American Language. The definition of "grown-up" is given in this dictionary reference as an adjective (which is how it is used in the claims) to mean "that is an adult" or "of, for, or like an adult". The immediately preceding

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definition for the term "grown" in "grown-up" is "having completed its growth; fully developed; mature". These dictionary definitions of "grown" and "grown-up" are consistent with the following exemplary descriptions in the specification:

The above-selected juvenile bodies of the transgenic carrot were planted in a test garden. The edible parts (underground tissues) were harvested from the carrots that had grown-up, and the harvested product was homogenized and extracted with the equal volume of an appropriate extraction buffer (pH 8.0). (emphasis added) (see specification, Example 2, page 20, lines 2-7).

The above-selected juvenile bodies of the transgenic lettuce were planted in a test garden. The edible parts (above ground parts) were harvested from the plants that had grown-up, and the harvested product was homogenized and extracted with the equal volume of an appropriate extraction buffer (pH 8.0) prepared in the usual manner. (emphasis added) (see specification, Example 3-2, page 23, lines 15-20).

Accordingly, the term "grown-up" recited in the claims is not indefinite.

Reconsideration and withdrawal of the rejection are therefore respectfully requested.

Claims 11-16, 18-19, and 32 have been rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. The examiner indicated that

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this is a new matter rejection because the term "grown-up" is not supported in the originally filed specification or claims. This rejection is respectfully traversed.

Applicants do not understand the examiner's position that the term in question, "grown-up", does not appear in applicants' cited support on pages 20 and 23 of the specification. The cited passages on pages 20 and 23 are provided above in response to the indefiniteness rejection with the term "grown-up" highlighted. Thus, a transgenic carrot or lettuce that had grown-up is the same as calling it a grown-up transgenic plant, which is exactly what is recited in the claims.

Reconsideration and withdrawal of the rejection are therefore respectfully requested.

Claims 11-16, 18 and 32 have been rejected under 35 U.S.C. §102(b) as being anticipated by Goodman et al., U.S. Patent 4,956,282. This rejection is respectfully traversed.

The examiner states that Goodman teaches transgenic tobacco plants (column 8, lines 50-63, especially lines 60-63). Goodman discloses at column 8, lines 60-63:

The plantlets were transferred to rooting medium containing kanamycin (100 IL g/ml) and most of the morphology normal plantlets rooted.

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It should be noted however that rooted plantlets of tobacco plants disclosed in Goodman should be distinguished from "grown-up transgenic plant" of the claimed invention. That is to say, "transgenic tobacco plants" disclosed in Goodman at column 8, lines 50-63 are "sterile tobacco plants" at the callus stage which were grown from leaf-disk (see column 8. lines 46-49). In Goodman, the "sterile tobacco plants" were inoculated with *A. tumefaciens* C58 (pCGN810) and then the calli were proliferated and rooting was promoted. Goodman's disclosure however stops there. Applicants therefore believe that the "transgenic tobacco plants" disclosed in Goodman are not the "grown-up transgenic plant" of the presently claimed invention.

As recited in independent claim 11, a grown-up transgenic plant of the presently claimed invention is a plant which is obtained by growing or regenerating the transformed plant protoplast, plant cell, plant tissue or calli into such a stage of development as to be recognized as, for example, tomato, lettuce, etc., according to the race of the transgenic plant. It is clear that the transgenic plant which is grown-up to such stage of development is distinct from the "transgenic tobacco plants" disclosed in Goodman.

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In view of the above discussion, the "grown-up transgenic plant" of the presently claimed invention should be distinguished from the "transgenic tobacco plants" disclosed in Goodman. It is also clear that the "callus" recited in Goodman is not a "grown-up transgenic plant" of the present invention.

Furthermore, it should be noted that Goodman does not recite that the "grown-up transgenic plant" in the sense of the present invention was obtained, whereas Goodman does state at column 8, lines 50-63 that calli were obtained and their rooting was promoted.

In short, "sterile tobacco plants", "sterile tobacco plants inoculated with *A. tumefaciens* C58 (pCGN810)" and "callus" disclosed in Goodman are all different from the "grown-up transgenic plant" of the presently claimed invention in both their production processes and forms. As applicants have repeatedly stated in previous responses, what is recited in column 5, lines 40-60 of Goodman using the words "may be" is just Goodman's hope or speculation, but is certainly not a disclosure, much less an enabling disclosure, that can be applied against the present claims.

Applicants note that the examiner has stated that the amount of cytokine in the grown-up transgenic plant in claim 11

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would have been an inherent property of the DNA construct used in Goodman and has no patentable weight. However, as argued above, Goodman does not disclose "grown-up transgenic plants" obtained from callus.

Applicants again wish to emphasize that Goodman only discloses "sterile tobacco plants inoculated with *A. tumefaciens* C58 (pCGN810)" and "callus". Goodman never states that a "grown-up transgenic plant" was actually obtained. In other words, Goodman has not completed his invention with respect to "grown-up transgenic plant". The subject-matter of Goodman's invention is to express mammalian peptide in plant cells. Applicants believe that a "grown-up transgenic plant" in which expressed mammalian peptides exist in an advanced stage of Goodman's invention had not been achieved.

Furthermore, in amended claim 1, a grown-up transgenic plant is specified as being edible for mammals and human. Applicants note that the examiner is of the opinion that "edible" plant is unclear because this necessarily refers to an organism for which the plant is an edible foodstuff. While the applicants do not agree with the examiner, in deference to the examiner, claim 11 has been amended to refer to an organism for which the plant is an edible foodstuff, i.e. "for mammals and humans".

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By contrast, a "tobacco plant" is considered in general not to be edible for mammals and humans. In this regard, a grown-up transgenic plant of the claimed invention is distinguished from what is disclosed in Goodman.

In fact, Goodman never teaches ingestion of a transgenic plant, in which cytokine is expressed, by the oral route. It is therefore not necessary for Goodman that a transgenic plant is edible. By contrast, as described in the instant "Summary of the Invention", the present invention was made to establish a novel way for administering cytokines. It is quite a novel idea that cytokine can be ingested through oral routes when the cytokine is expressed in an edible plant. As shown in Example 3-2 at pages 22-24 of the specification, a grown-up transgenic lettuce expressing interferon- $\alpha$  was fed to mice and exhibited enhanced immunological potency of the mice. In Example 4-2, at pages 25-27, in particular, a grown-up transgenic strawberry expressing erythropoietin was fed to mice and showed inherent activity of erythropoietin while an isolated preparation of erythropoietin did not show any apparent effect (see page 27 of the specification). This advantage of the present invention would not have been expected from the disclosure of Goodman.

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Goodman therefore cannot and does not anticipate the presently claimed invention.

Reconsideration and withdrawal of the rejection are therefore respectfully requested.

Claims 11-16, 18-19, and 32 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Goodman in view of Vogel et al., J. Experimental Botany, 52:1817-1826 (2001). The examiner states that the teachings of Goodman are discussed in the §102(b) rejection above and admits that Goodman does not teach further supplementation with trehalose. However, the examiner holds that the addition of sugars to food is well known and is a design choice well within the means of one of ordinary skill in the art without any surprising or unexpected results. The examiner therefore concludes that the present invention is *prima facie* obvious in view of Goodman and Vogel. This rejection is respectfully traversed.

Attached hereto is a certified English translation of the Japanese priority document JP 200195/2000 filed June 30, 2000. As the applied Vogel et al. was published in 2001, after the priority date claimed and perfected by the certified English translation, Vogel is not available as prior art. Accordingly,



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the presently claimed invention cannot be made obvious by Goodman alone.

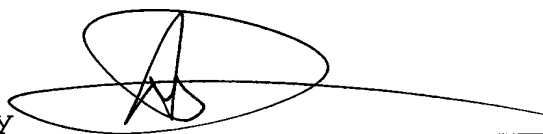
Moreover, Vogel does not disclose the "grown-up transgenic plant" of the present invention but merely discloses a plant which inherently contains trehalose.

Reconsideration and withdrawal of the rejection are therefore respectfully requested.

In view of the above, the claims comply with 35 U.S.C. §112 and define patentable subject matter warranting their allowance. Favorable consideration and early allowance are earnestly urged.

Respectfully submitted,

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